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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,500	12/02/2004	Juan Luis Hancke Orozco	Herbal Powers	4925

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EXAMINER

RAHMANI, NILOOFAR

ART UNIT	PAPER NUMBER
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1625

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/516,500

Applicant(s)

HANCKE OROZCO ET AL.

Examiner

Niloofer Rahmani

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In view of the appeal brief filed on 08/01/2006, PROSECUTION IS HEREBY REOPENED. The grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

2. The rejection of claim 73 for "Andrographis Panculata" under 112, first paragraph is withdrawn in view of applicant's amendment.

3. The rejection of claims 53-73 for "diagnosing in a patient a disease selected from the group consisting of Alzheimer's disease; Acquired immune deficiency syndrome; autoimmune disease; syndrome X" under 112, first paragraph is withdrawn in view of applicant's argument. Smith et al., Molecular and Cellular Biochemistry, Vol. 263, pages

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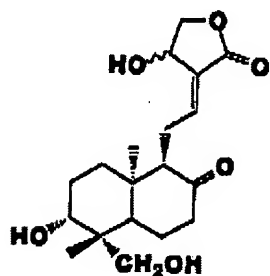
189-210 has shown the nexus between the cellular activity (PPAR- γ receptor) and the treatment of syndrome X and inflammatory cytokine and TNF- α . Milterski et al., Genes and Immunity, Vol. 3, pages 211-219 has shown the nexus between the NFKB cascade and autoimmune disease. Daly et al., American Society for Clinical Nutrition, Vol. 66, pages 1072-85 disclosed that insulin resistance is associated with diabetes mellitus, ischemic heart disease, and hypertension both independently and as part of syndrome X.

4. The rejection of claims 53, 65-72 under 35 U.S.C. 102(b) over Boggs et al., US 5,883,074 is withdrawn in view of applicant's argument. Boggs et al. has shown the activity as antibacterial agents not AID's, Alzheimer's disease, autoimmune disease.

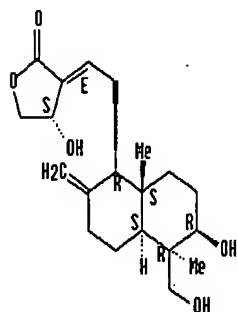
5. The rejection of claims 53, 66-72 under 35 U.S.C. 102(b) over Panossian et al., Phytomedicine, Vol. 9, pages 598-605 is withdrawn in view of applicant's argument. Panossian et al. has shown the activity as TNF- α not AID's, Alzheimer's disease, autoimmune disease.

6. The rejection of claims 53-73 under 35 U.S.C. 102(b) over Babish et al., US 2002/0068098 is maintained for the reason of record. Applicants argue that the structure disclosed in the prior art is not the same as the structure in the instant application. It is the examiner's position that the (=O) in the prior art structure on sheet 2, Fig. [B3]

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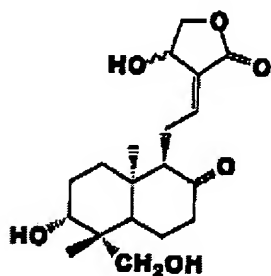
is typo. Babish et al. on page 4 has shown that Andrographolide is obtained from the same family of plant *Androgra Phispaniculata* having the activity such as anti-inflammatory, Alzheimer's disease, antihyperlipidemia. Therefore, since this reference repeat the name "Andrographolide" over and over, then the structure of "Andrographolide" on sheet 2 should be the same as the structure from the STN REGISTRY



7. The rejection of claims 53-54, 63, and 66-72 under 35 U.S.C. 102(b) over Wheelock et al., US 5,833,994 is maintained for the reason of record. Applicants argue that the structure disclosed in the prior art is not the same as the structure in the instant application. It is the examiner's position that the structure that applicants mentioned could not be found in the US 5,833,994. Wheelock et al. disclosed on column 21, lines 49-52, the compound "Andrographolide" which is extracted from the *Andrographis Paniculata* plant which has activity as treating AID's, anticancer, HIV, viral infection.

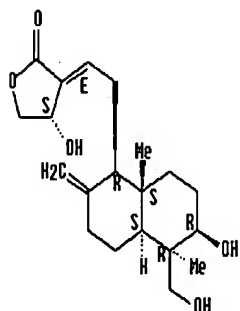
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8. The rejection of claims 53-73 under 35 U.S.C. 102(b) over Babish et al., US 2002/0077350 is maintained for the reason of record. Applicants argue that the structure disclosed in the prior art is not the same as the structure in the instant application. It is the examiner's position that the (=O) in the prior art structure on sheet 2, the compound [C3]



is typo. Babish et al. on page 5 has shown that Andrographolide is obtained from the same family of plant *Andrographis Paniculata* having the activity such as anti-inflammatory, Alzheimer's disease, antihyperlipidemia, antitumor, colon cancer. Therefore, since this reference repeat the name "Andrographolide" over and over, then the structure of "Andrographolide" on sheet 2 should be the same as the structure from the

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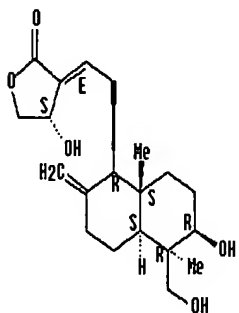


9. The rejection of claims 53-54, 65-72 under 35 U.S.C. 102(b) over Wheelock et al., US 6,140,063 is maintained for the reason of record. Applicants argue that the

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structure disclosed in the prior art is not the same as the structure in the instant application. It is the examiner's position that the structure that applicants mentioned could not be found in the US 6,140,063. Wheelock et al. disclosed on column 22, lines 35-38, the compound "Andrographolide" which is extracted from the Andrographis Paniculata plant which has activity as treating AID's, anticancer, HIV, viral infection.

10. The rejection of claims 53-54, 64-72 under 35 U.S.C. 102(b) over Babish et al., WO 96/17605 is maintained for the reason of record. Applicants argue that the structure disclosed in the prior art is not the same as the structure in the instant application. It is the examiner's position that the structure that applicants mentioned could not be found in the WO 96/17605. Babish et al. disclosed on page 16, lines 25-26, the compound "Andrographolide" which is purchased from Aldrich Chemicals having activity as Alzheimer's, AID's. Therefore, the structure used as "Andrographolide" is

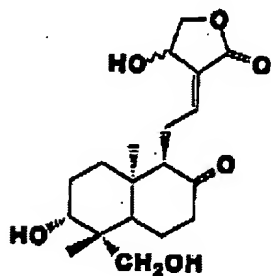


not the

structure that applicants mentioned in the Appeal Brief.

11. The rejection of claims 53-54, and 65-72 under 35 U.S.C. 102(b) over Wheelock et al., WO 98/30213 is maintained for the reason of record. Applicants argue that the structure disclosed in the prior art is not the same as the structure in the instant application. It is the examiner's position that the structure that applicants mentioned

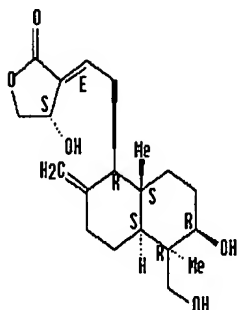
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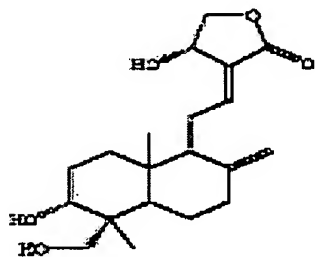
could not be found in WO 96/17605. Wheelock et al. on page 32

has shown that Andrographolide is obtained from the same family of plant *Andrographis Paniculata* having the activity such as AID's, HIV, and cancer. Therefore, since this reference repeat the name "Andrographolide" over and over, then the structure of "Andrographolide" should be the same as the structure from the

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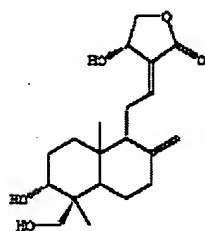


12. The rejection of claims 53-54, and 66 under 35 U.S.C. 102(b) over Nanduri et al., US 6,410,590 is maintained for the reason of record. Applicants argue that the structure disclosed in the prior art is not the same as the structure in the instant application. It is the examiner's position that the structure on column 8, lines 10-25, the compound of formula (II)



anticipates the instant compound claimed which is obtained from the same family of plant *Andrographis Paniculata* (column 2) having the activity such as autoimmune diseases, AID's, HIV, and cancer. Therefore, since the structure and the name is the same as the instant claims, there is no difference.

13. The rejection of claims 53-54, 64-72 under 35 U.S.C. 102(b) over Nanduri et al., US 6,486,196 is maintained for the reason of record. Applicants argue that the structure disclosed in the prior art is not the same as the structure in the instant application. It is the examiner's position that the structure that applicants mentioned could not be found in the US 6,486,196. Nanduri et al. disclosed on column 2, the compound "Andrographolide"

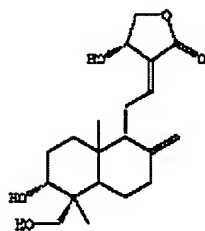


, which is extracted from the same family of plant *Andrographis Paniculata* having activity as Alzheimer's, AID's, HIV, and anticancer. Therefore, since the structure and the name is the same as the instant claims, there is no difference.

14. The rejection of claims 53-54, 65-72 under 35 U.S.C. 102(b) over Nanduri et al., US 2002/0016324 is maintained for the reason of record. Applicants argue that the

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structure disclosed in the prior art is not the same as the structure in the instant application. It is the examiner's position that the structure that applicants mentioned could not be found in the US 2002/0016324. Nanduri et al. disclosed on column 1, the compound "Andrographolide"



, which is extracted from the same family of plant Andrographis Paniculata having activity as AID's, HIV, psoriasis, cardiovascular disorders, and anticancer. Therefore, since the structure and the name is the same as the instant claims, there is no difference.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Mckenzie, can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

01/05 /2007

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